

**REMARKS**

Applicants respectfully request reconsideration of the present application in view of the reasons which follow.

***I. Introduction***

Upon entry of the above amendment, claims 1-13 will be pending. Applicants have revised claim 1 to prescribe that a toxic material or substance is released from a biological organism. Support for the amendment can be found throughout the specification, for example, at page 9, 1<sup>st</sup> full paragraph.

Applicants also have revised claim 7 to clarify that the "said" refers to "dendrimer." Claim 12 has been revised to define "toxic material or substance" of claim 1 more specifically. Applicants have added claim 13 to define further "biological organism" of claim 1. Support for claim 13 can be found throughout the specification, for example, at page 9, 1<sup>st</sup> full paragraph.

***II. Rejection under 35 USC §112, Second Paragraph***

The examiner has rejected claim 7 on the basis that it is unclear what the "said" refers to. In response, applicants have revised claim 7 to recite "said dendrimer" to clarify that the "said" refers to "dendrimer" of claim 2. Because the revision of claim 7 renders the rejection moot, applicants respectfully request withdrawal of the indefiniteness rejection.

***III. Rejection under 35 USC §102(b)***

The examiner has maintained the rejection of claims 1-12 as allegedly anticipated by Matthews *et al.* (WO 95/34595). While recognizing the distinction between virus and a toxic material or substance released from the virus, *i.e.*, antiviral activity vs. anti-toxin activity, the examiner contends that the claims as previously amended in view of the specification still appear to read on method of inhibiting viral activity. Applicants respectfully disagree.

According to the specification, the term "toxic materials or substances" is intended to refer in particular to toxins of biological (animal, plant, microbial or viral) origin. As explained in the previous response, "toxin" is understood to be "a colloidal poisonous substance that is a specific product of the metabolic activities of a living organism and is usually very unstable, notably toxic protein when introduced into the tissues, and typically capable of inducing antibody formation." MERRIAM-WEBSTER MEDICAL DICTIONARY. That is, a toxin is not an "infectious agent" such as virus. The specification makes it clear that "toxic materials or substances" in the instant application refer to toxins of biological (animal, plant, microbial or viral) origin, not a biological organism such as animal, plant, microorganism, or virus *per se*. The examples of the "toxic materials or substances," (in particular, other materials or substances released during bacterial infection such as bacterial endotoxins and exotoxins, or during protozoal, fungal or viral infection) further underscore the exclusion of the biological organism such as virus from the "toxic materials or substances" of the claimed invention. Thus, reading the specification taking into account the common knowledge in the relevant art, one of ordinary skill in the art would have easily recognized that the "toxic materials or substances" of the claimed invention do not encompass infectious agent such as virus. In consequence, the claims do not read on a method for viral treatment disclosed in Matthews *et al.*

The examiner's mistaken interpretation of the specification is itself sufficient basis for withdrawing the anticipation rejection. In an effort to further emphasize the feature of toxic materials or substances in this regard, however applicants have revised claim 1 to recite that "toxic material or substance is released from a biological organism." Because this amendment simply clarifies the claimed invention, it would not change the scope of the claims previously presented. Therefore, applicants respectfully request entry of this amendment.

As applicants have noted above, therefore, Matthews *et al.* does not teach each and every element of the claimed method of inhibiting the activity of a toxic material/substance, and thus does not qualify as an anticipation of claims 1-12. Accordingly, reconsideration and withdrawal of the subject rejection are respectfully requested.

**IV. Double Patenting Rejection**

The examiner has maintained the rejection of claims 1-12 under the judiciary created doctrine of obviousness-type double patenting in view of claims 1-38 of U.S. Patent No. 6,190, 650 ("the '650 patent").

Applicants respectfully submit that the examiner's rationale for rejection should not stand in light of the distinctions that pertain in this context as elaborated above. In particular, applicants would emphasize that claim 1 as revised, further clarifies the distinction between a claimed method of inhibiting the activity of a toxic material/substance, and a method for antiviral treatment. For the reasons developed previously, the skilled artisan would have differentiated an inhibition of toxic effects from an antiviral treatment. Therefore, claims 1-12 are patentably distinct from claims 1-38 of the '650 patent. Accordingly, reconsideration and withdrawal of the double-patenting rejections are respectfully requested.

In view of the foregoing amendment and remarks, applicants respectfully request favorable reconsideration and allowance of the pending claims. If there are any issues remaining which the examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the examiner hereby respectfully invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

Date 27 March 2003

By Stephen A. Bent

FOLEY & LARDNER  
Customer Number: 22428  
\*22428\*  
22428

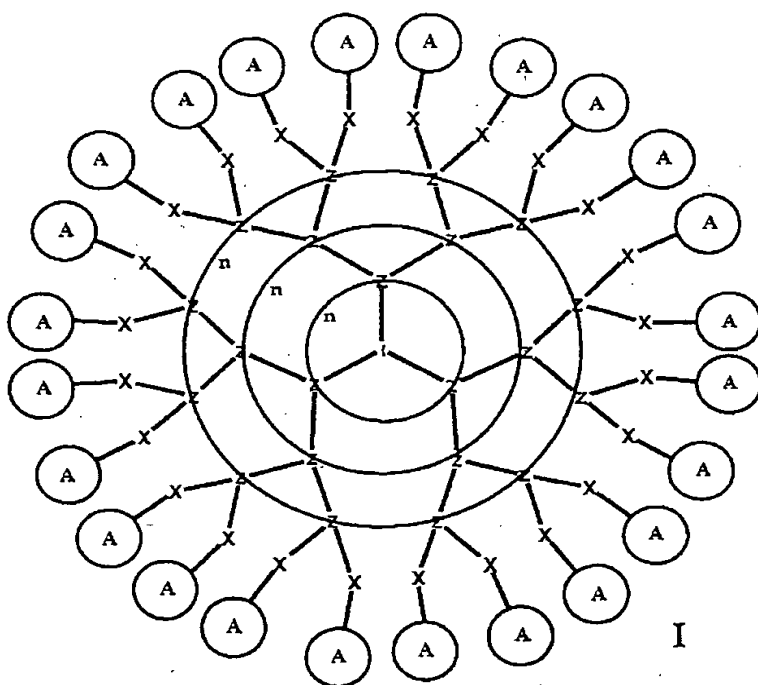
Stephen A. Bent  
Attorney for Applicants  
Registration No. 29,768

PATENT TRADEMARK OFFICE  
Telephone: (202) 672-5404  
Facsimile: (202) 672-5399

**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

1. (Twice Amended) A method of inhibiting the activity of a toxic material or substance in a human or non-human animal patient, which comprises administration of the patient of an effective amount of a dendrimer having a plurality of terminal groups wherein at least one of said terminal groups has an anionic- or cationic-containing moiety bonded or linked thereto and wherein said toxic material or substance is released from a biological organism.

7. (Twice Amended) A method according to claim 2 wherein said dendrimer is a polyionic dendrimer of the general formula I:



wherein:

I is an initiator core;

Z is an interior branching unit;

n is an integer which represents the number of generations of the dendrimer; and

A is an anionic- or cationic containing moiety which may be linked to interior branching unit

Z through an optional linking group X.

12. (Twice Amended) A method according to claim 1, wherein said [method comprises inhibition of] toxic material or substance is selected from the group consisting of (1) toxins and toxic peptides of biological origin, [or] and toxins and toxic peptides released during bacterial, protozoal, fungal or viral infection.